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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,643	03/23/2004	Aaron V. Kaplan	015471-000910US	3899

7590 08/24/2006
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EXAMINER

SCHILLINGER, ANN M

ART UNIT PAPER NUMBER

3738

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/807,643	Applicant(s) KAPLAN ET AL.	
	Examiner Ann Schillinger	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 15 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 November 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/12/04, 6/10/05</u> | 6) <input type="checkbox"/> Other: _____ |

6/24/05, 4/3/06

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 23-24 and 27-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Globerman (U.S. Application No. 2005/0288769). Globerman discloses the following regarding claim 23: a prosthesis (110) for placement at an os opening (104) from a main body lumen (100) to a branch body lumen (102); said prosthesis comprising: a radially expansible scaffold (300; paragraph 0015) having at least a first wall pattern (302 or 1100); and at least two circumferential (paragraph 0006, U.S. Pat. No. 5,607,444 which is incorporated by reference) anchors (306) extending axially from an end of the scaffold (Figure 3), said anchors adapted to extend axially into and expandably circumscribe at least one-half of the main vessel wall when the scaffold is implanted in the branch lumen with said one end adjacent the os (Figure 1D; paragraph 0006, U.S. Pat. No. 5,607,444 which is incorporated by reference), said prosthesis additionally having a region with a second wall pattern (304 or 1104) that is

Art Unit: 3738

different from the first wall pattern, said second wall pattern permitting the anchors to both bend (308; paragraph 0042) and rotate (paragraph 0119) relative to the prosthesis (Figures 1A-1D, 3, 11). Based on the Applicant's specification, the word "rotate" is interpreted as the anchors being able to move in a slanted or diagonal direction. Such movement is disclosed by the Globerman reference where the anchors can move obliquely.

Globerman discloses the following regarding claim 24: a prosthesis comprising at least three anchors extending axially from the end of the scaffold (paragraph 0093).

Globerman discloses the following regarding claim 27: a prosthesis wherein the scaffold comprises a plurality of axially adjacent cells (306; Figure 3).

Globerman discloses the following regarding claim 28: a prosthesis wherein the circumferential anchors are all congruent (paragraph 0093).

Globerman discloses the following regarding claim 29: a prosthesis wherein the circumferential anchors will radially expand when the scaffold is radially expanded (paragraph 0090).

Globerman discloses the following regarding claim 30: a prosthesis further comprising a radiopaque marker at or near the region with the second wall pattern (210; Figure 2).

Globerman discloses the following regarding claim 31: a prosthesis mounted on a balloon wherein the balloon has a radiopaque marker aligned with the region between the scaffold and the circumferential anchors (paragraph 0006, U.S. Pat. No. 5,607,444 that is incorporated by reference).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Globerman. Globerman discloses the claimed invention except for the specific lengths of the anchors claimed by the Applicant. It would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the anchors to any desired length because it would provide tailor anchors for varying sized vessels or organs as noted in paragraphs 0110 and 0137. It has been held that finding an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F. 2d 272, 205 USPQ 215 (CCPA 1980).

Claims 32-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Globerman in view of Vardi et al. (U.S. Application No. 2002/0116047). Globerman does not disclose the use of one stent to open a lumen or vessel for the insertion of another stent. Vardi et al. teaches this in paragraph 0046. Globerman discloses the following regarding claim 32: a method for deploying a prosthesis across an Os opening from a main lumen to a branch lumen said

Art Unit: 3738

method comprising: positioning a prosthesis so that a scaffold lies within the branch lumen and at least two circumferential anchors extend into the main lumen (Figure 1C-1D); radially expanding the scaffold to implant said scaffold in the branch lumen (Figure 1D); circumferentially deforming the anchors such that at least one of said anchors bends and rotates relative to the prosthesis (Figure 1D; paragraph 0100), said deforming causing the anchors to circumscribe at least a portion of the main lumen wall and open a passage through the anchors (Figures 1D, 2). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a stent to open the vessel for the second stent to be properly positioned. Globerman discloses the rest of the dependent claims as described below.

Globerman discloses the following regarding claim 33: a method wherein at least three circumferential anchors extend into the main lumen (paragraph 0123).

Globerman discloses the following regarding claim 34: a method wherein positioning the first prosthesis comprises aligning a visible marker (210) on at least one of the prosthesis (110) and a delivery balloon with the Os (202; Figure 2).

Globerman discloses the following regarding claim 35: a method wherein the lumens are blood vessels (paragraph 0024).

Globerman discloses the following regarding claim 36: a method wherein the scaffold is expanded with a balloon expanded within the scaffold (paragraph 0029).

Globerman discloses the following regarding claim 37: a method wherein the anchors are deformed by expanding a balloon positioned transversely between through the anchors (paragraph 0029).

Globerman discloses the following regarding claim 38: a method wherein the scaffold and anchors are expanded and deformed by the same balloon (paragraph 0029).

Globerman discloses the following regarding claim 39: a method where the scaffold and anchors are expanded and deformed by different balloons (page 1, paragraph 0006, U.S. Pat. No. 5,868,777 that is incorporated by reference).

Globerman discloses the following regarding claim 40: a method wherein the second prosthesis is deployed by a balloon catheter exchanged over a guidewire pre-positioned for deformation of the anchors (page 1, paragraph 0006, U.S. Pat. No. 5,607,444 that is incorporated by reference).

Globerman discloses the following regarding claim 41: a method wherein the anchors are deformed by deployment of the second prosthesis (paragraph 0091).

Globerman discloses the following regarding claim 42: the deployed second prosthesis supports the anchors over their lengths from the Os over the main lumen wall (paragraph 0100).

Response to Arguments

Applicant's arguments filed on March 28, 2006 have been fully considered but they are not persuasive. Applicant contends that Globerman does not

Art Unit: 3738

disclose the anchors extending axially into and expandably circumscribe at least one-half of the main vessel. However, the Examiner is interpreting the words "adapted to" as functional language. It has been held that the recitation that an element "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. If the stent in Figure 1D of the Globerman reference is moved further out towards the main vessel, the anchors would be capable of extending axially into and expandably circumscribe at least one-half of the main vessel. *In re Hutchinson*, 69 USPQ 138. Additionally, U.S. Pat. No. 5,607,444 that is incorporated by reference into Globerman discloses the circumferential anchors, which are capable of circumscribing at least one-half of the main vessel where the stent is located. Regarding the insufficient size of Globerman's flaring section, Globerman discloses in paragraphs 0110 and 0137 that the sizes of specific parts of the stent may be altered to fit accordingly with any vessel or lumen.

Applicant's arguments with respect to claims 25-26, 31, 32-41 have been considered but are moot in view of the new ground(s) of rejection.

The Information Disclosure Statement has been considered and included in this office action.

In view of the amendments to the specification and the claims, the objections to the specification and the drawings, and the 35 U.S.C. 112 rejection to Claim 42 have been withdrawn.

Art Unit: 3738

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Schillinger whose telephone number is (571) 272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ann Schillinger
August 9, 2006

A. Stewart
ALVIN J. STEWART
PRIMARY EXAMINER

